Illinois Department of Human Services

George Ryan, *Governor*

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Howard A. Peters III, *Secretary*

**Office of Alcoholism and Substance Abuse**
100 W. Randolph St. - Ste. 5-600
Chicago, Illinois 60601-3297

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(HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 106 1)
Rockville, MD 20857
[Docket No. 98N-0617]

To Whom It May Concern:

We are responding to the Federal Register Notice of July 22, 1999, on proposed rules to repeal the existing Narcotic Treatment Regulations as enforced by the Food and Drug Administration, in addition to creating a new accountability system based on the principles of an accreditation model. The State of Illinois currently licenses 43 methadone programs and services 9230 methadone patients. In addition, Illinois licenses all outpatient, residential, and detox programs as well as recovery homes, and DUI programs.

In Illinois, we are faced with an ever increasing demand for methadone services. It is clear that the federal government and its various agencies must assist the states in their current and proposed responsibilities in the monitoring and funding of narcotic treatment programs. There is a renewed interest in methadone treatment in Illinois from areas which were either neutral or firmly against it just a few years ago. We are to working with the Department of Children and Family Services to assist their case workers and the court systems to learn more about methadone treatment while, attempting to dispel the many myths involving methadone treatment. Until recently, case workers and judges required mothers to cease their methadone treatment in order to retain or regain custody of their children. In most cases, their methadone treatment was the most stabilizing influence in their lives. Taking away the medication and the support of the treatment program forces many children to remain in foster care as wards of the state. This renewed interest will initiate additional demands on our treatment system.

Illinois is also working with the City of Chicago's Department of Public Health with the Capacity Expansion Project and in training and education to promote methadone treatment activities, These positive activities will also stimulate the demand for additional narcotic treatment services.

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While there are clearly too few treatment slots available now, this new interest and interaction in methadone treatment will negatively effect an already overburdened Illinois treatment system. As with other states, Illinois needs additional treatment dollars, while recognizing its renewed responsibility to monitor the quality of the services being provided.

## ACCREDITATION

The State of Illinois fully supports the idea of an accrediting body in treatment reform which can be seen as a logical next step from the State Methadone Treatment Guidelines in maintaining a reliable standard for methadone treatment.

While supporting the idea of an accrediting body, Illinois would appreciate the opportunity to explore the possibility of becoming its own accrediting body. The proposed rules allow States which license 50 or more narcotic treatment programs to apply to become their own accrediting body. Currently this would allow only three states; New York, California, and Texas this opportunity. The State of Illinois currently licenses 43 Narcotic Treatment Programs. We would request that number lowered to 40. This would increase the number of States eligible to become accrediting bodies to a total of only five or 11.6% of the programs offering maintenance treatment. Lowering the number to 30 would increase the number by only an additional two states to a total of seven or 16.3% of the programs which provide methadone maintenance.

## COSTS OF ACCREDITATION

While supporting the idea of accreditation, the issue of the increased costs of accreditation cannot be ignored. The direct cost of accrediting a methadone program appears to range from $7,500 to $11,000 based on data submitted to AMTA. Estimates of the additional costs such as improvements to physical plants, staff time to improve program procedures and manuals, additional staff, and computer upgrades run from $26,000 to $45,000. More accurate fiscal information may be forthcoming from the accreditation pilot studies now underway and should be carefully reviewed.

Illinois supports the AMTA call for a multi year, multipurpose federal fund to ensure that methadone treatment programs and patients will not be adversely affected by the implementation of accreditation standards, decreasing access to care through program closures. This fund would be used to cover the costs of application, surveys, toxicology as well as the costs of technical and financial support for the implementation of improvements as the direct result of accreditation surveys.

## TAKE HOME MEDICATION

Illinois supports modifying current take home medication requirements and urges FDA to adopt a variation within Option 2. This variation allows clients to have a single take home dose during the first month in treatment, two take homes doses during the second month in treatment, up to five take home doses in the third month of treatment, and in the remaining months of the first year of treatment, the maximum take home supply is three doses after each supervised ingestion. Programs would be allowed to dispense up to a fourteen day supply of medication after one year in treatment and up to a thirty-one day supply of medication after two years, providing the patient has met other criteria as stipulated in the Proposed Rule

Illinois however has reservations about an up to thirty-one day supply of medication for even the most stable client and may consider amending state regulations to limit medication to a fourteen day limit. Illinois believes that such a large number of take homes may present the risk of diversion or worse, increase the opportunity of accidental ingestion by other members of a patient's household.

## LAAM

Illinois supports the revocation of the restrictions on LAAM take homes, the use of LAAM in patients under 18, and the initial and periodic pregnancy testing to patients of childbearing potential, to allow more room for clinical judgement and based on the experience gained by programs in their use of LAAM over the past four years. Illinois is not currently a large user of LAAM but it welcomes any approved treatment regimen or drug which promotes successful patient outcomes.

## DETOXIFICATION

Illinois supports the elimination of a waiting period between each detoxification admission. We agree that the 7 day waiting period, originally designed to guard against de facto maintenance treatment, is more time than is needed for this purpose and may unnecessarily expose patients to increased risks from HIV and other diseases and unnecessary discomfort. FDA has historically approved a high volume of exception requests from program physicians requesting a waiver of the waiting period. Since this is and has been the case, we question the maintenance of an the artificial waiting period and the corresponding high volume of unnecessary paperwork.

## TOXICOLOGY

The State of Illinois currently provides toxicology tests for its funded programs through a contract with an independent laboratory, While we support the increase in the number of required toxicology tests beyond the first year as a treatment issue, it is estimated that this increase in the requirement will cost Illinois, or its individual programs, an additional $155,000 per year which is currently unavailable to either group. Please refer to the Costs of Accreditation section above.

## OFFICE-BASED OPIATE TREATMENT

The State of Illinois firmly supports the process of physician-based Medical Maintenance for the stabilized methadone client as described in the recent, CSAT OBOT Position Paper. Illinois has already participated in an FDA-approved Medical Maintenance research project run by Dr. Edward Senay. The results clearly confirmed the theory that stable methadone treatment clients could continue to be successful with a minimum of program contact.

Illinois also supports office-based opiate treatment for areas that are far removed from existing programs making treatment extremely difficult for potential patients in these area. Specific support would have to be based on distances from existing programs and criteria and procedures for the appropriate monitoring of individual physicians approved to dispense methadone for addiction treatment.

Illinois thanks you for this opportunity to comment on the propose rules and looks forward to working with FDA, CSAT, and the accrediting bodies toward the positive future of methadone treatment.

Sincerely,

Nick Gantes

Nick Gantes
Associate Director
Office of Alcoholism and Substance Abuse

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